|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening Date** | | **Screening Attempt** | **PTID** | | | **Staff Initials/Date** | **Enrollment Date  (or NA if not enrolled)** | | **Screen Failure Date (or N/A if enrolled)** | | | **Screening Failure/ Discontinuation Codes (or N/A if enrolled)** | | | **Staff Initials and Date** |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
|  | |  |  | | |  |  | |  | | |  | | |  |
| **Screening Failure/Discontinuation Codes** | | | | |  | |  |  | |  |  | |  |  | |
| **I1** | Not born female | | | **I10** | Not willing to refrain from participation in other studies | | **E1f** | FTM hormone use/anticipated | | **E2** | Participation other study within 60 days | | **E4h** | INR >1.5x site lab ULN | |
| **I2** | Not 18-45 (inclusive) | | | **E1g** | Chronic vaginal candidiasis | | **E3** | Uncontrolled/chronic condition (IoR/designee) | | **E5** | Is pregnant | |
| **I3** | No informed consent | | | **I11** | Irregular menses | | **E1h** | Syphilis, GC or CT within 6 months | | **E4a** | AST or ALT grade 1 or higher | | **E6** | Diagnosed with UTI | |
| **I4** | Inadequate locator | | | **I12** | Not willing to abstain from non-study products | | **E1i** | Last pregnancy outcome within 90 days | | **E4b** | Creatinine clearance <60mL/min | | **E7** | Diagnosed with PID/STI/RTI requiring treatment | |
| **I5** | HIV-positive | | | **E1a** | Known adverse reaction to study products | | **E1j** | Currently breastfeeding | | **E4c** | Hemoglobin grade 1 or higher | | **E8** | Pelvic finding grade 1 or higher | |
| **I6** | Not in good health | | | **E1b** | IVDU within 12 months | | **E1k** | Had a hysterectomy | | **E4d** | Platelet count grade 1 or higher | | **E9** | Severe pelvic relaxation | |
| **I7** | Not willing to be abstinent | | | **E1c** | PEP within 6 months | | **E1l** | Intends pregnancy | | **E4e** | WBC grade 2 or higher | | **E10** | Any other condition (IoR/designee) | |
| **I8** | No contraceptive | | | **E1d** | PrEP within 6 months | | **E1m** | Plans to relocate | | **E4f** | Hepatitis B positive | |  |  | |
| **I9** | ≥21 y.o: unsatisfactory Pap | | | **E1e** | CYP3As use/anticipated | | **E1n** | Known HIV positive partner | | **E4g** | Hepatitis C positive | |  |  | |